

Stem Cell Center

The **Stem Cell Center (SCC)** supports stem cell focused process development, manufacturing, preclinical safety testing, and other activities needed to successfully apply to the FDA for approval to start a clinical trial. The SCC includes the **Translating Center**, which supports activities related to cell process development, manufacturing and research necessary to obtain an Investigational New Drug (IND) application – a prerequisite for clinical testing of cell therapy product candidates and the **Accelerating Center** which supports IND submissions and clinical trials for projects. Both CIRM-funded centers were awarded to QuintilesIMS in 2016, creating the SCC.

The QuintilesIMS SCC offers end-to-end pre-clinical, consulting, clinical development and commercialization services. Additionally, the SCC draws upon the expertise and operational excellence of world class organizations such as Charles River Laboratories and City of Hope for pre-clinical research and CMC services, respectively. The SCC offers services in the areas of:

- **Pre-IND and IND-enabling preclinical/nonclinical services** – pharmacology and toxicology studies, process development, manufacturing
- **IND-filing and clinical start-up services** – regulatory documentation, IND development and filing services, protocol development, IB generation
- **Clinical conduct services** – clinical operations, safety monitoring, site selection and patient recruitment
- **Commercial services** – health economics and outcomes research studies, real-world evidence strategy, pricing and market access assessments
- **Project management services** – project management support to coordinate efforts across project stakeholders, ensure project stays on track and meet its milestones. For more information about CIRM project manager requirements, **refer to this PDF**.

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For a more detailed overview of Stem Cell Center services, please refer to the following document:

- **Stem Cell Center Core Services (2017) (PDF)**

Contacting the SCC

To inquire about SCC services, please contact:

- **Email:** StemCellCenter@quintilesims.com
- **Phone:** +1 (844) 399-5698

- **Address:** 10188 Telesis Court Suite 400, San Diego, CA 92121

*If you are contacting the SCC regarding CIRM translational awards or applications and would like CIRM input on eligibility, please include **translational@cirm.ca.gov** with your correspondence to the SCC.

If you are contacting the SCC regarding CIRM clinical awards or applications and would like CIRM input, please include **clinical@cirm.ca.gov.

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